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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WOITACH, JOSEPH T

ART UNIT PAPER NUMBER

1632

DATE MAILED: 04/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,240

Applicant(s)

YAN ET AL

Examiner

Joseph T. Woitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1/14/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4, 7-82 and 84-91 is/are pending in the application.
- 4a) Of the above claim(s) 7-69, 74, 76-79, 81 and 85-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 70-73, 75, 80, 82-84 and 89-91 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application claims benefit to provisional application 60/253943, filed November 30, 2000.

Applicants' amendment filed December 15, 2004, was non-compliant with respect to the claim listing. However, the amendment to the specification was entered.

Applicants' amendment filed January 14, 2005, has been received and entered. Claims 1, 5, 6 and 83 have been canceled. Claims 2, 3, 70, 72, 75, 82 and 84 have been amended. Claims 89-91 have been added. Claims 2-4, 7-82, 84-91 are pending.

The arguments provided in the non-compliant amendment filed December 15, 2004 are currently under consideration.

Election/Restriction

Applicant's election without traverse of Group I, claims 2-4, 70-73, 75, 80, 82, 84, in the reply filed on March 30, 2004 was acknowledged. No arguments have been provided in the instant amendment.

Claims 2-4, 7-82, 84-91 are pending. Newly added claims 89-91 are drawn to the elected invention. Claims 7-69, 74, 76-79, 81, 85-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Claims 2-4, 70-73, 75, 80, 82-84, 89-91 drawn to an isolated homozygous stem cell, are currently under examination.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 15, 2004 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Specification

The nucleotide sequence disclosure contained in this application complies with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825.

The amendments to the specification have addressed the basis of the objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4, 70-73, 75, 80, 82-84 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn.

Upon review of the amendment to the claims to delete "derived" and in view of Applicants' arguments, Examiner would agree that the claims are not indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4, 70-73, 75, 80, 82-84 stand rejected and newly added claims 89-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Thomson *et al.* (Science 1998-IDS reference).

Claims 2-4, 70-73, 75, 80, 82-84 stand rejected and newly added claims 89-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Doetschman *et al.* (J. Embryol. Exp. Morph 1985-IDS reference).

Claims 2-4, 70-73, 75, 80, 82-84 stand rejected and newly added claims 89-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Evans *et al.* (Nature 1981-IDS reference).

Claims 2-4, 70-73, 75, 80, 82-84 stand rejected and newly added claims 89-91 are rejected under 35 U.S.C. 102(b) as being anticipated by Saito *et al.* (Dev. Biol. 1992-IDS reference).

Applicants summarize the requirements for making a rejection under 35 USC 102, specifically that each and every limitation must be present in the prior art reference, citing

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Verd gall Bros. v. Union Oil Co. in support of their assertion. Summarizing the cell described in each of the cited references, Applicants argue that the methods used by the references would not provide the homozygosity of the described cell. Applicants arguments have been fully considered, but not found persuasive.

The claims under examination are generally drawn to an isolated homozygous stem cell, are currently under examination, while claims 5, 6, 70-73, 75, 80 and 82-84 are produced by particular methods. The issue is whether the methods disclosed in the instant specification result in a stem cell that is materially different from that in the cited art. Initially, it is noted that the specification provides a definition of a "homozygous stem cell" as a cell previously termed a teratoma stem cell or a cell made by a variety of methods, including the isolation of stem cells as the cells isolated from the inner cell mass of blastocyst-like masses (see bottom of page 16). Newly added claims 89-91 set forth three parameters of homozygous as in haplotypes, alleles and units of genetic material. Initially, given the definition provided in the instant specification or even a comparison of parameters such as haplotype, allele, stem cells obtained from an individual or from a embryo made by IVF would have common haplotype, alleles or genetic units. A unit of genetic material is a very broad term and could reasonably be interpreted to be any genetic sequence. It appear that Applicants are attempting to define the term of homozygosity to be identical pairs of chromosomes, however even their methodology would not produce such a cell. During meiosis, recombination occurs between chromosomes such that each of the resulting germ cell is different from one another. Thus, even the product by process claims were two germ cells are recombined back into one cell, the method would result in a cell that indistinguishable from those in the cited art. Applicants have simply argued that the cited

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references do not teach that the stem cells are homozygous without providing any clear scientific basis for why the claimed cell can be distinguished from these stem cells.

As noted previously, where, as here, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. See *In re Ludtke* 441 F.2d 660, 169 USPQ 563 (CCPA 1971). Whether the rejection is based on "inherency" under 35 USC 102, or "*prima facie obviousness*" under 35 USC 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products. *In re Best, Bolton, and Shaw*, 195 USPQ 430, 433 (CCPA 1977) citing *In re Brown*, 59 CCPA 1036, 459 F.2d 531, 173 USPQ 685 (1972).

Thomson *et al.* teach the isolation and characterization of human embryonic stem cells.

Doetschman *et al.* teach the isolation and characterization of mouse embryonic stem cells.

Evans *et al.* teach the isolation and characterization of mouse embryonic stem cells.

Saito *et al.* teach the isolation and characterization of bovine embryonic stem cells.

For the reasons above and of record, the rejections are maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

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harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-4, 70-73, 75, 80, 82-84 stand rejected and newly added claims 89-91 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5, 7-14 of copending Application No. 10/179959.

Applicants indication that a terminal disclaimer will be filed is noted (page 23), however the rejection can not be held in abeyance, and is maintained for the reasons of record.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Woitach

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